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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,158	08/30/2001	David T. Bailey	HAU234	8638

7590
Sarah O'Rourke
Hogan & Hartson, LLP
Suite 1500
1200 17th Street
Denver, CO 80202

11/04/2003

EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/04/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,158

Applicant(s)

BAILEY ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 14-28, 61, 62, 65, 66 and 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 14-28, 61, 62, 65, 66, and 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-9, 11, 14-28, 61-62, 65-66, 69-72 are pending.

Claims 1-28, 61-62, 65-66, 69-72 have been rejected.

Claims 10, 12-13, 29-60, 63-64, and 67-68 have been canceled.

Specification

The objection has been withdrawn due to the modification made in the amendment.

Claim Objections

The objection of claims 20 and 44 has been withdrawn due to the modification made in the amendment.

Claim Rejections-35 USC 112

1. Applicants' argument filed 8/8/2003 have been fully considered but they are not persuasive.

The rejection of Claims 1, 14, and 24 under 35 USC 112, first paragraph, has been maintained due to applicants' failure to change in the amendment, whereas the rejection of Claims 36, 39, 48, 54, and 58 under 35 USC 112, first paragraph has been withdrawn due to the modification made in the amendment.

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The rejection of Claims 9, 25, 29, 33, 49, 55 and 59 under 35 USC 112, second paragraph, has been withdrawn due to the modification made in the amendment.

Claim Rejections-35 USC 102

Rejection of claims 61-62 under 35 U.S.C. 102(b) as being anticipated clearly by Levy et al (U.S. 5,780,060) has been changed to rejection of Claims 61-62 under 35 U.S.C. 103(a) as being unpatentable over Levy et al (U.S. 5,780,060) in view of S.O.R.I.(GB 1,235,379).

Claims 65-66 under 35 U.S.C. 102(b) as being anticipated clearly by Gabetta et al (U.S. 5,200,186) has been changed to rejection of Claims 65-66 under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of S.O.R.I.(GB 1,235,379).

Claim Rejections-35 USC 103

The rejection of Claims 1-9, 11, 14-28 under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of and S.O.R.I.(GB 1,235,379).

The rejection of Claims 1-9, 11, 14-28 under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of S.O.R.I.(GB 1,235,379) is maintained for the reasons of the record in paper no. 5.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 61-62 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al (U.S. 5,780,060) in view of S.O.R.I.(GB 1,235,379).

Levy et al discloses a dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15 % of anthocyanidines (see col. 13, lines 61-63).

The instant invention ,however, differs from the Levy et al reference in that the brominated polystyrene resin is employed .

Furthermore, S.O.R.I. discloses a process for extracting anthocyanines from certain berries and fruits by using extraction solvents, such as water ,methanol, ethanol or butanol or any mixture thereof (see page 2 , lines 32-35). During the process of yielding juice, pectinase can be added to the crushed fruits (see page 1, 39-45). Furthermore, the composition of the unpurified extract may contain 27 to 30 % of anthocyanins, traces of aglycone, monosaccharides, traces of pectins, and organic ions (see page 2 ,lines 55-68). The pre-concentrated liquid and juice may be treated by means of ion exchange resins to form anthocyanin cations. These cations can be selectively fixed by anionic resins. The recovery of anthocyanins happens in the strong acidic medium, such as hydrochloric acid (see page 2 ,lines 75-81).

Concerning the use of the brominated polystyrene resin ,in the process, S.O.R.I. does indicate the broad use of the ion exchange resins to which the brominated polystyrene resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Furthermore, this does not have any patentable weight over

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the prior art reference. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use as an alternative in order to enhance the process .

Both references have commonly shared the process of preparing the certain concentration range of anthocyanosides. Levy et al does disclose the formation of dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15 % of anthocyanidines. Also, S.O.R.I. does point out that the pre-concentrated liquid and juice may be purified by means of ion exchange resins to form anthocyanin cations, which, in turn, these cations can be fixed by anionic resins in order to obtain anthocyanins. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to incorporate the teaching of S.O.R.I.'s anionic resins into the Levy et al process , thereby enhancing the purification process of anthocyanins. This is because the skilled artisan in the art would expect the combined processes to increase the purity of the desired compound as well as to have a similar success as shown in the S.O.R.I. process.

Claims 65-66, and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabetta et al (U.S. 5,200,186) in view of Langston (U.S. 4,500,556) and S.O.R.I.(GB 1,235,379).

Gabetta et al discloses a commercial *Vaccinium myrtillus* extract contains 35 % of anthocyanosides (see col. 3 ,lines 45-46) , which can be used in a therapy in the pathology of capillaries and in the ophthalmology (see coil. 1 ,lines 12-15). Besides anthocyanosides and

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aglycones (see col. 1 ,lines 16-18), it may have mineral salts, common organic acids, and etc.
(see col. 1 ,lines 27-30).

Furthermore, Gabetta et al teaches a method of preparing a high concentration of anthocyanosides from the fruits of *Vaccinium myrtillus*, *Ribes nigrum*, *Vitis vinifera*, *Sambucus*, and other plants (see col. 1, 11-12) in the following steps of :

- a. extracting *Vaccinium myrtillus* fruits with 50 % aqueous methanol;
- b. adding sodium bisulfite to the solution;
- c. charging the solution to a non-polar polystyrenic resin;
- d. washing the column with 8 liter of water, thereby eluting anthocyanosides;
- e. concentrating the eluted aqueous solution under vacuum;
- f. acidifying the aqueous solution with 1% hydrochloric acid solution;
- g. extracting the aqueous solution with butanol;
- h. washing the resultant solution with HCl solution; and
- i. precipitating the solid and being dried under vacuum (see col. 3, example 1).

As a result of the process, the extract of anthocyanosides contains the following composition (%): delphinidin galactoside 13.20, delphinidin glucoside 15.00, delphinidin arabinoside 9.06, cyanidin galactoside 7.25, cyanidin glucoside 9.06, cyanidin arabinoside 4.41, petunidin galactoside 3.88, petunidin glucoside 9.07, petunidin arabinoside 1.94, peonidin galactoside 0.65, peonidin glucoside 3.45, peonidin arabinoside 0.24, malvidin galactoside 3.02, peonidin glucoside 9.06, peonidin arabinoside 0.95 (see col. 3 ,lines 30-40).

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Furthermore, during the extracting step, a polar organic solvent immiscible with water is used(see col. 3 ,lines 30-40).

The instant invention ,however, differs from the Gabetta et al reference in that a purified bilberry extract comprises 8-12 % anthocyanins by weight of the extract; the brominated polystyrene resin is employed .

Furthermore, S.O.R.I. discloses a process for extracting anthocyanines from certain berries and fruits by using extraction solvents, such as water ,methanol, ethanol or butanol or any mixture thereof (see page 2 , lines 32-35). During the process of yielding juice, pectinase can be added to the crushed fruits (see page 1, 39-45). Furthermore, the composition of the unpurified extract may contain 27 to 30 % of anthocyanins, traces of aglycone, monosaccharides, traces of pectins, and organic ions (see page 2 ,lines 55-68). The pre-concentrated liquid and juice may be treated by means of ion exchange resins to form anthocyanin cations. These cations can be selectively fixed by anionic resins. The recovery of anthocyanins happens in the strong acidic medium, such as hydrochloric acid (see page 2 ,lines 75-81).

Concerning the use of the brominated polystyrene resin ,in the process, Gabetta et al does indicate the broad use of the non-polar polystyrenic resin to which the brominated polystyrene resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Furthermore, this does not have any patentable weight over the prior art reference. Therefore, it would have been obvious to the

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skillful artisan in the art to have motivated to use the brominated polystyrene resin as an alternative in order to enhance the process .

With respect to the difference in the anthocyanins concentration in the extract, the limitation of a process with respect to ranges of pH, time and concentration does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Concentration is well understood by those of ordinary skill in the art to be a result-effective variable , especially when attempting to control selectivity of a chemical process.

Both references have commonly shared the process of preparing the high concentration of anthocyanosides from the fruit by means of extraction and ion exchange resins. Gabetta et al does teach the general method of preparing the high concentration of anthocyanosides from the various fruits by extracting the fruits containing anthocyanines in the presence of the polar organic solvent by means of the non-polar polystyrenic resin. And S.O.R.I. does point out that the pre-concentrated liquid and juice may be purified by means of ion exchange resins to form anthocyanin cations, which, in turn, these cations can be fixed by anionic resins in order to obtain anthocyanins. Therefore, it would have been obvious to the skillful artisan in the art to have motivated to incorporate Langston's filtration step prior to contacting ion exchange resins in the Gabetta et al process ,along with the use of S.O.R.I.'s anionic resins, thereby enhancing the purification process of anthocyanins. This is because the skilled artisan in the art would expect the combined processes to increase the purity of the desired compound as well as to have a similar success as shown in the S.O.R.I. process.

Response to Applicants' Argument

1. Gabett teaches adding a source of bisulfite ions and Langston teaches the use of bisulfite ions, which are irrelevant due to the modification made in the amendment;
2. None of the cited references disclose the use of a brominated polystyrene resin ;
3. the S.O.R.I reference does not teach the use of a brominated polystyrene resin ; therefore, the use of an anion exchange resin is irrelevant to the current invention.

First, with respect to the first argument, the Examiner has been withdrawn from the rejection based on the Langston reference. Therefore, the issue is also irrelevant.

Second, regarding the second and third arguments, the Examiner has noted applicants' argument. However, concerning the use of a brominated polystyrene resin which yields an unexpected result, the primary Gabetta et al reference does indicate the broad use of the non-polar polystyrenic resin to which the brominated polystyrene resin may be belonged. Furthermore, there is little difference between their respective functionalities during the purification processes. Moreover, attorney's arguments of unexpected results can not take the place of evidence in the record. In re DeBlauwe, 736 F. 2d 699, 705, 222 USPQ 191, 196 (Fed.

Cir. 1984). Therefore, it would have been obvious to the skillful artisan in the art to have motivated to use the brominated polystyrene resin as an alternative in order to enhance the process in the absence of an unexpected result.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

November 2, 2003


D. MARGARET SEAMAN
PRIMARY EXAMINER